DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
M3202n
Food and Drug Administration
New Orleans District Office
Nashville Branch
297 Plus Park Blvd.
Nashville, TN 37217

November 19, 1999

11/23/99

CERTIFIED MAIL- RETURN RECEIPT REQUESTED

WARNING LETTER-00-NSV-04

FACILITY ID #133868

Terry Gunn, Administrator
Riverpark Hospital
1559 Sparta Road
McMinnville, TN 37110

Dear Mr. Gunn:

Your facility was inspected on November 9, 1999 by a representative of the State of Tennessee on contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 1

Phantom QC records were missing for 4 weeks for unit 1. [redacted], Room Mammo Room 1.

Level 2

Phantom QC records were missing for at least two weeks but less than four weeks for unit 2, [redacted] Room Mammo Room 2.

The phantom QC is not adequate for unit 2, [redacted], Room Mammo Room 2 because the operating level for background density was less than 1.20 optical density.

2 of 5 random reports reviewed did not contain an assessment category for site Riverpark Hospital.

These specific deficiencies appear on the Post Inspection Report, which was given to your facility at the close of your inspection. These deficiencies are symptomatic of serious problems that could compromise the quality of mammography at your facility and potentially overexpose both patients and employees involved with mammography.

Riverpark Hospital
Terry Gunn, Administrator

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies that the inspection identifies and to promptly initiate permanent corrective actions.

If you fail to properly address these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of similar violations.

If your facility is unable to complete the corrective actions within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Joseph E. Hayes, Compliance Officer, U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125. Any questions in regard to this letter or how to ensure you are meeting MQSA standards, please call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,

James E. Gamet
Director
New Orleans District

JEG/krs

cc: State of Tennessee

Melissa Wolford, Environmental Assistance Center, 540 McCallie Avenue, Suite 550
Chattanooga, TN 37401-2013